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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

October 27, 1999

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Md. 20852

RE: Docket Number 99N-3089
Draft Agenda for International Activities

The Cosmetic, Toiletry, and Fragrance Association is the national trade association that has represented the cosmetic industry for over a century. Our membership includes 285 manufacturers and distributors of cosmetic products as well as 300 suppliers of raw materials, packaging and other goods and services used by the industry.

Most of our members are engaged in international trade and therefore are interested in the Draft Affirmative Agenda For International Activities of the Center for Food Safety and Applied Nutrition (CFSAN).

We are pleased that the Center has asked for comments on the subject of the proper role for its international activities.

The draft agenda raises a number of issues which we would like to address.

Introduction To The Draft Agenda

CFSAN states in the introduction to its draft that the Center is "presented with the dilemma of accomplishing FDA's primary public health mission while assisting other components of the United States government and other stakeholders with issues relating to international trade of food and cosmetics."

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One need not sacrifice one goal for the other. It is our view that FDA can balance its resources sufficiently so that they can participate in many more international activities than they have in the past.

Many of the activities where we seek FDA participation involve obtaining an equal playing field for US companies in the international marketplace.

CFSAN also states in its introduction that "most international activities undertaken by CFSAN will be based on their potential to impact positively on U.S. public health protection." Such a benchmark was often impossible to meet and too often FDA was not at the table when their expertise could contribute to the dialogue on many issues affecting the cosmetic industry.

We submit that a better benchmark would be that FDA will participate in international activities provided that no negative impact on US public health could be shown to result from their participation and that the resources are available to them.

We would now like to address some of the specific priorities laid out in the paper and juxtapose them against activities we believe FDA should become engaged in with regard to cosmetics.

International Harmonization

CFSAN indicates in its draft paper that it will contribute scientific expertise toward development of international standards. We are pleased that FDA has identified this general topic as one of its priorities and more specifically that it will contribute its expertise to international standards development. For the cosmetic industry there are several such activities currently underway which in our view fall under this proposed mandate.

The Transatlantic Business Dialogue (TABD) and the Transatlantic Economic Partnership (TEP) are two forums for discussion of issues relating to the international concerns of the cosmetic industry. We encourage FDA to become key players in both these efforts. FDA should also try to ensure that the technical experts who are responsible for the daily regulatory oversight of cosmetics are in attendance at these meetings. Most often they are not.

The other forum where harmonization discussions are underway is in the Cosmetics Harmonization and International Cooperation(CHIC) meetings. These meetings include government representatives from the EU, Japan, the US and Canada.

The first meeting was held in April of this year and we understand that follow-up meetings will be held as well. We want to applaud CFSAN for their active participation in these meetings and encourage that participation to continue. A number of difficult issues were identified for future discussions, including finding ways to speed up approval of products such as sunscreens in the respective markets. We are hopeful that this effort will lead to improved efficiencies in the not too distant future.

We would also like to commend the agency for its willingness to involve representatives from both CFSAN and CDER (The Center For Drug Evaluation and Research) in these discussions.

The TABD, the TEP and CHIC activities involve attempts to harmonize the regulatory systems around the world. This need not mean as FDA has often put it "a dumbing down " of their regulatory responsibilities. It does mean recognizing that there may be other ways to achieve FDA's goals which are different from what is currently being done.

Investigate Alternatives To Animal Testing

We support FDA's decision to make this issue a priority as well. Animal testing is a key concern to consumers, government and the industry alike. Any move to alternatives should be scientifically based and give the same assurances of establishing safety that FDA has placed in animal tests. There are efforts in the European Union to ban animal tests for cosmetics. As early as June 2000 rules limiting the sale of cosmetics tested on animals after that date could be in place in the European Union. It is important therefore that FDA become actively engaged in the discussions on alternatives.

Provide Timely Technical Assistance to U.S. Trade Agencies

CFSAN has indicated that they see a role for themselves in this area. We are pleased to note that FDA has also identified facilitating and developing mutual recognition agreements as one of the aspects of forwarding this goal.

We have heard in the recent past that FDA would not favor such efforts. If mutual recognition agreements are under consideration once again than we would welcome the opportunity to discuss this issue for cosmetics.

In addition, in the area of international trade disputes, we would like to note that on two occasions when there were hearings involving trade sanctions against cosmetic imports, an FDA representative was not present at the formal interagency panel hearing on the matter. We would suggest that FDA should become more visible in such hearings. Their voice could clarify certain issues for other members of the panel.

Certificates Of Free sale

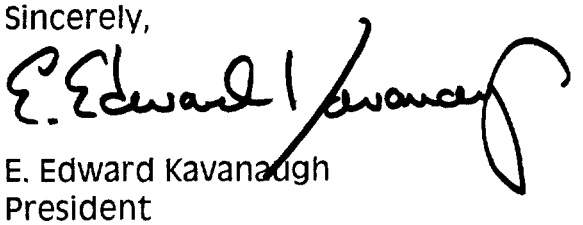
CFSAN states that it will "issue certificates for export or provide for alternative methods for such certificate". Over the years we have worked with FDA to ensure that there is an alternative method for issuing Certificates of Free Sale. CTFA issues over 1400 of such certificates each year.

FDA's recognition of the ability of CTFA to issue such certificates is greatly appreciated and we are always willing to work with FDA to continue to be able to provide this service to our members. Our involvement and cooperation with FDA has ensured that FDA resources can be devoted to other tasks without jeopardizing the confidence that foreign governments place in the Certificate of Free Sale.

We believe that the CTFA certificate of free sale program should continue to function as an alternative program.

We appreciate the opportunity to offer our suggestions on the draft affirmative agenda and would be pleased to provide any additional information on the issues raised herein.

Sincerely,



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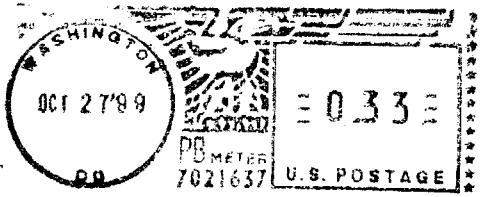

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